

## REMARKS

Applicants wish to thank the Examiner for the time and care taken in acting on the instant application in the paper mailed November 13, 2007. Claims 1-21 as previously presented are pending herein. Minor amendments are requested of Claim 1.

The Examiner has apparently objected to the disclosure due to certain informalities. The Examiner has rejected claims 1-6, 8, 13-14 and 15-17 and 20 under U.S.C. § 103(a) as unpatentable over Illum, U.S. Patent No. 5,863,554 in view of Ko, et al. (Journal of Microencapsulation, 1998). Claim 7 has been rejected as obvious and unpatentable over Illum in view of Ko as applied above and further in view of Patel. Claims 9-10, 12 and 18-19 have been rejected as obvious and unpatentable over Illum, Ko and Dondeti. Claim 11 has been rejected as obvious and unpatentable over Illum, Ko and Glass.

Applicants traverse each and every rejection to the extent that they may be maintained by the Examiner.

Applicants have traversed the Examiner's rejection of Claims 1-6, 8 and 13-14 under 35 U.S.C. § 103(a) as being unpatentable over Illum (U.S. Pat. No. 5,863,554), in view of Ko, et al. (Journal of Microencapsulation 1998).

The Examiner has maintained the rejection based on Illum combined with Ko. Illum is relied upon as teaching a composition containing lipophilic carrier within Applicant's claimed range. In specific, the Examiner cites Illum at Col. 7, lines 14 through 55 as disclosing the alleged lipophilic system.

However, this disclosure is incomplete. Within the cited passage, there is no disclosure of any active agent. In fact, it is only at Illum Col. 8, lines 4 through 22 that the final formulation is prepared. At this point, the concentration of lipophilic carrier is well below 50% w/v. (Notably, the only complete system formulated by Illum is that containing albumin.

This is well outside of the claimed ranges. To interpret Illum in the manner suggested by the Examiner would seem to make the reference incomplete and nonsensical.

The Examiner has apparently added the teachings of Ko to show the use of testosterone in nasal applications. However Ko does not remedy the deficiencies of Illum. Notably, Ko teaches the creation of an oil phase with roughly 45% (parts-by-weight) of soybean oil (pg. 199).

Neither Illum nor Ko teach the use of such high concentrations of lipophilic agents with the active. For example, Illum teaches the use of as much as 10% phospholipids (col. 4, lines 18-26) to enhance membrane permeability (col. 6, lines 19-37).

The cited art simply does not suggest, teach or otherwise disclose the claimed invention.

Applicant has traversed the Examiner's rejection of dependent Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Illum (U.S. Pat. No. 5,863,554), in view of Ko, et al. (Journal of Microencapsulation 1998) as applied to claims 1-6, 8, 13 and 14 above, and further in view of Patel, et al. (U.S. Patent No. 6,248,363).

The Examiner further cited Patel as teaching that drug bio-availability can be improved by microglycerides and surfactants. However, the Examiner has failed to show how Patel remedies the deficiencies of Illum and Ko (earlier cited). Patel does not teach a high lipophilic concentration.

Accordingly, the present rejection also fails. Favorable reconsideration of the rejected claims is respectfully requested.

Applicant has traversed the Examiner's rejection of dependent Claims 9-10, and 12 under 35 U.S.C. § 103(a) as being unpatentable over Illum (U.S. Patent No. 5,863,554), in view of Ko, et al. (Journal of Microencapsulation 1998) as applied to claims 1-6, 8, 13 and 14 above, and further in view of Dondeti (International Journal of Pharmaceutics, 1996).

The Examiner has further cited Dondeti as teaching formulation parameters that affect nasal absorption of drugs. The rejected claims are dependent on earlier rejected claim 1. Apart from problems with Dondeti teaching solid compositions and not liquids, Dondeti does nothing to remedy the deficiencies of Illum and Ko (earlier cited). Since the Examiner has done nothing to show how Dondeti cures the deficiencies of Illum and Ko in the earlier rejection, the present rejection also fails.

Applicants respectfully request favorable reconsideration of the rejected claims.

Applicants have traversed the Examiner's rejection of claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Illum (U.S. Patent No. 5,863,554), in view of Ko, et al. (Journal of Microencapsulation 1998) and further in view of Glass (U.S. Pat. No. 5,897,894). The Examiner has further cited Glass as teaching liquid oils which can be thickened to increase viscosity. Claim 11 is dependent upon earlier rejected claim 1, in series. The Examiner has failed to show how Glass remedies the deficiencies of Illum and Ko, (also earlier cited), and thus fails to show how the cited references meet the claimed invention. Again, the high lipophilic concentration is absent.

Favorable reconsideration is respectfully requested.

## CONCLUSION

Favorable reconsideration of all claims pending herein is respectfully requested. The Examiner is invited to contact Applicant's representative (below) if questions arise.

Respectfully submitted,

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